Food and Drug Administration, HHS

preruminating calves. Do not use in calves to be processed for veal.

[40 FR 13838, Mar. 27, 1975, as amended at 58 FR 6092, Jan. 26, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 8371, Feb. 25, 1997; 62 FR 23357, Apr. 30, 1997; 62 FR 35076, June 30, 1997; 62 FR 40932, July 31, 1997; 63 FR 59714, Nov. 5, 1998; 64 FR 18572, Apr. 15, 1999; 70 FR 73137, Dec. 9, 2005; 71 FR 13542, Mar. 16, 2006; 74 FR 60156, Nov. 20, 2009; 76 FR 17337, Mar. 29, 2011; 77 FR 56770, Sept. 14, 2012; 78 FR 17596, Mar. 22, 2013]

§ 520.2220b Sulfadimethoxine tablets and boluses.

- (a) *Sponsors*. Approval to firms identified in §510.600(c) of this chapter as follows:
- (1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.
- (2) To 000061, approval for use as in paragraph (d)(2).
- (b) Related tolerances. See §556.640 of this chapter.
- (c) [Reserved]
- (d) Conditions of use—(1) Cattle—(i) Amount. Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.
- (ii) Indications for use. For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Fusobacterium necrophorum sensitive to sulfadimethoxine.
- (iii) Limitations. Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.
- (2) Dogs and cats—(i) Amount. Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours.
- (ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- (3) Beef cattle and nonlactating dairy cattle—(i) Amount. Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.
- (ii) Indications for use. Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as Pasteurella spp. sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with Fusobacterium necrophorum sensitive to sulfadimethoxine.
- (iii) Limitations. Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999; 70 FR 16934, Apr. 4, 2005; 76 FR 17337, Mar. 29, 2011]

§ 520.2220c Sulfadimethoxine oral suspension.

- (a) Chemical name. N'-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.
- (b) *Specifications*. Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.
- (c) *Sponsor*. See Nos. 000061 and 000069 in §510.600(c) of this chapter.
- (1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.
- (2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during the treatment period.
- (3) For use only by or on the order of a licensed veterinarian.
- [40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]